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08/026,736 03/05/93 ALIZON

M 3495.0010-12

EXAMINER

FEISEE, L

ART UNIT

PAPER NUMBER

12

1806

DATE MAILED:

09/20/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 8/4/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 11, 13, 15 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-10, 12, 14, 16 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 11, 13, 15 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. 158652; filed on 2/22/88.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1806

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The finality of the previous Office Action is withdrawn in view of the new Ground of Rejection which will be set forth below.

The rejection of claims 11,13 and 15 under 35 USC 101 as lacking diagnostic utility is maintained for reasons previously set forth. The rejection is mainly applicable for the portion of the claim relating to the use of the antibodies to the tat protein. tat is the product of a spliced gene and the antibodies which have been shown in the references of Gallo and Arya et. al. are against the entire spliced gene. There is no convincing evidence that the product of the sequence in the claims would yield a tat product which can elicit antibodies that are of diagnostic value, for reasons adequately discussed in paper #10.

NEW GROUNDS FOR REJECTION

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1806

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure, ie. failing to show how to make and or use the claimed invention.

The claims are drawn to antibodies which bind to gene products of particular open reading frames of HIV-1. The specification has essentially sequenced the HIV-1 genome and identified particular open reading frames or ORFs. The specification also in general terms describes the production of antibodies specific for the gene product of these ORFs for diagnostic application. The specification however, does not discuss the possibility of split ORFs in producing a particular gene product. It is now known that *tat* is a product of two different ORFs, however, this was not known at the time the invention was made. Applicant cannot use the work of others to enable his specification. At the time the invention was made, very little was known about the gene products encoded by the HIV ORFs. It was quite likely that any or all of the ORFs of a virus could be split, ie. joined through recombination. Also, it was not clear what form of expression or the expression system would have been capable of appropriately expressing the various gene products. The specification fails to provide enablement in the form of guidance in determining how to effectively make the claimed antibodies, through appropriate analysis and expression of the gene products. One of ordinary skill in the art would

Serial Number: 08/026,736

-4-

Art Unit: 1806

have been forced into undue experimentation to make the claimed invention as the specification was not enabling at the time the invention was made.


Claims 11, 13 and 15 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lila Feisee whose telephone number is (703) 308-2731. The examiner can normally be reached on Mondays-Fridays from 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Lacey, can be reached on (703) 308-3535. The fax number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lila Feisee/lf
September 19, 1994


DAVID L. LACEY
SUPERVISORY PATENT EXAMINER
GROUP 180
9/19/94